REMARKS

Claims 21-29 presently appear in this case. No claims have been allowed. The official action of August 13, 2002, has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to a method for treating autoimmune and inflammatory diseases by administering a TNF receptor in combination with DHEA.

The examiner has deemed the restriction requirement proper and made it final. As the election was made without traverse, non-elected claims 18-20 have now been deleted without prejudice toward of prosecution thereof in a divisional application. Once the examiner determines that claim 21 is allowable, then both species should be examined. Thus, while claims 22-24 are currently withdrawn from consideration, it is understood that they will be examined once the elected species is found to be allowable.

Claims 21 and 25-29 have been rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3-5 of U.S. patent 6,225,300. The examiner states that a timely filed terminal disclaimer may be used to overcome this ground of rejection.

Attached hereto is a terminal disclaimer of the present application with respect to the term of U.S. patent

6,255,300. In view of the filing of this terminal disclaimer, the present rejection has now been obviated. Reconsideration and withdrawal thereof are respectfully urged.

The examiner states that the incorporation of essential material in the specification by reference to a foreign application or patent or to a publication is improper. The examiner states that applicants' attempt to incorporate by reference the subject matter of the foreign patents that set forth the sequence of the TNF inhibitory protein is inappropriate as the sequence of the TNF inhibitory protein is essential for the method for treating autoimmune and inflammatory diseases in a patient by administering such a protein. Therefore, the examiner considers these foreign patent documents to encompass essential subject matter, and the examiner requires that the essential subject matter be physically incorporated into the present specification. This requirement is respectfully traversed.

European patents 308 378, 398 327 and 433 900 do not incorporate essential subject matter. As of the effective filing date of the present application on July 14, 1995, TBP-1 and TBP-2 were known polypeptides. The sequence of TBP-1, for example, is directly correlated to its name, and anyone of ordinary skill in the art could determine the sequence merely by

knowing the name. It should be noted that the Written Description Guidelines at MPEP §2163.A.2. state:

> Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement. Information which is well known in the art need not be described in detail in the specification. See, e.g., *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986).

See also MPEP §2164.01, relating to the enablement requirement, where it states:

> A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 920 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (2987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

Thus, merely by referring to these known polypeptides by name is an implicit disclosure of the known sequences that correspond thereto. Thus, it is not necessary physically to incorporate by reference the sequences of any of the cited patents. These patents are merely cited as background, letting those of ordinary skill in the art know where they can find the sequence, which is implicitly present in the name of the polypeptides which have been provided.

Furthermore, EP application 433 900 corresponds to U.S. patent 5,811,261. A review of the two specifications will show they are the same. Accordingly, page 1 of the present

specification has now been amended to substitute reference to the U.S. patent for reference to the European application. To the extent that incorporation by reference is necessary for this sequence, it is satisfied by reference to a U.S. patent. See MPEP §608.01(p)I.A.1. A copy of this U.S. patent is attached hereto.

It should further be noted that the parent application has now issued as U.S. patent 6,225,300. No objection was made to the disclosure of TBP-1 or TBP-2 during the prosecution of that case. As no such objection was raised in the parent case, it should not be raised in this case, as this would call into question the validity of an issued U.S. patent with an identical specification. For all of these reasons, reconsideration and withdrawal of this requirement are respectfully urged.

Claims 21 and 25-29 have been rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for a method for treating autoimmune and inflammatory disease in a patient by administering r-h-TBP-1 in combination with DHEA, does not reasonably provide enablement for a method for treating autoimmune and inflammatory diseases in a patient which comprises administration of any functional derivatives of TNF receptor or TBP-1 in combination with DHEA. The examiner states that the specification does not enable any person skilled in the art to practice the invention commensurate in scope with

these claims. The examiner states that the claims are overly broad in the recitation of "TNF receptor" and "TBP-1" since insufficient guidance is provided as to which of the myriad of polypeptide species encompassed by the claims will retain the characteristics of TNF receptor or TBP-1 and function in the claimed method. The examiner states that these terms encompass functional derivatives of the TNF inhibitory protein, referring to EP 308 378, page 11, line 40. This rejection is respectfully traversed.

It is not understood why the examiner states that the terms "TNF receptor" or "TBP-1" encompass functional derivatives. The cited EP 308 378 does not support this conclusion. Page 11, lines 42-44, of this patent states:

> The TNF Inhibitory Protein, salts, functional derivatives and active fractions thereof and mixtures of any of the foregoing are indicated for antagonizing the deleterious effects of TNF in mammals, i.e. for treating conditions wherein excess of TNF is formed endogenously or is exogenously administered.

It is clear from this sentence that "TNF Inhibitory Protein", which is now known as TBP-1, is disclosed separately from its salts, its functional derivatives and its active fractions. Patent EP 308 378 does not state that the definition of "TNF Inhibitory Protein" includes functional derivatives. The sequence of TBP-1 is known. There is nothing in the present specification which indicates that this term encompasses a

"myriad of polypeptide species". It only includes the species known for this name.

It should be understood that this argument is not intended to limit the claims in any way from the language as originally submitted. It merely explains that the examiner is incorrect in interpreting this term as literally encompassing a myriad of polypeptide species. The sequence for TBP-1 is clearly set forth in U.S. patent 5,811,261, which is attached hereto. Nothing in the present specification suggests that the term is intended to literally encompass functional derivatives. Reconsideration and withdrawal of this rejection are, therefore, respectfully urged.

Claims 21 and 25-29 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such as a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed had possession of the claimed invention. The examiner states that the claims are genus claims and that the terms "TNF receptor" and "TBP-1" encompass functional derivatives. This rejection is respectfully traversed.

As stated hereinabove, the present claims do not literally encompass functional derivatives. Accordingly, the premise for this rejection is faulty for the reasons discussed

above. Once it is understood that the present claims do not literally encompass functional derivatives, the present rejection becomes moot. Reconsideration and withdrawal thereof are, therefore, respectfully urged.

Claims 21 and 25-29 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The examiner states that the claims are incomplete for omitting essential steps in that there is no result step set forth in the claim.

Claim 21 has now been amended to specify that the result of the administration is "treating the autoimmune or inflammatory disease". Accordingly, the claim now incorporates the result, thus obviating this rejection. Reconsideration and withdrawal thereof are respectfully urged.

It is submitted that all the claims now present in the case clearly define over the references of record. Reconsideration and allowance are, therefore, earnestly solicited.

Respectfully submitted,

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